

**Notice of Allowability**

Application No.

10/635,342

Examiner

Hector M. Reyes

Applicant(s)

BAMAUNG ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/13/05.
2. ☒ The allowed claim(s) is/are 1,2,6 and 16, renumbered as 1-4.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**DETAILED ACTION**

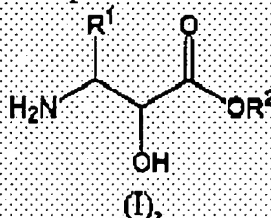
**Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gregory Donner on April 13, 2005. Please amend the claims as follows:

IN THE CLAIMS

1. (currently amended)[[:]] A compound of formula (I)



or a therapeutically acceptable salt thereof, wherein

$\text{R}^1$  is selected from the group consisting of alkyl, alkylsulfanylalkyl, aryl, arylalkyl, cycloalkyl, (cycloalkyl)alkyl, and hydroxyalkyl; and

$\text{R}^2$  is selected from the group consisting of hydrogen, alkenyl, alkyl, alkylcarbonyloxyalkyl, alkylcarbonylalkyl, aryl, arylalkyl, cycloalkyl and (cycloalkyl)alkyl.

2. (original)[[:]] The compound of claim 1 wherein  $\text{R}^2$  is hydrogen.

3-5 cancelled

6. (currently amended)[[:]] The compound of claim 5 selected from the group consisting of 1 which is

~~(2R,3R)-3-amino-4-cyclohexyl-2-hydroxybutanoic acid;~~

~~(2R,3R)-3-amino-3-cyclohexyl-2-hydroxypropanoic acid;~~

~~(2R,3R)-3-amino-2-hydroxy-5-phenylpentanoic acid;~~

~~(2S,3R,4S)-3-amino-2-hydroxy-4-(3-hydroxypropyl)-7-methyloctanoic acid; and~~

~~(2S,3R)-3-amino-2-hydroxy-6-phenylhexanoic acid.~~

7-15 (cancelled)

16. (original)[[:]] A pharmaceutical composition comprising a compound of claim 1, or a therapeutically acceptable salt thereof, in combination with a therapeutically acceptable carrier.

claims 17-18 (cancelled)

### **Status of the Claims**

Claims 1, 6 and 16 have been amended. Claims 3-5; 7-15 and 17-18 have been canceled. Currently claims 1, 2, 6 and 16 are under Examination. Examiner has renumbered the said claims as claims 1-4.

### **Allowance**

The following is an examiner's statement of reasons for allowance.

Applicants claim a series of hydroxyalkyl derivatives as described in claims 1-3 and pharmaceutical compositions comprising the same as described in renumbered claim 4.

No prior art disclosing or suggesting any of the listed compounds was found. The closest art relevant to Applicant's instant invention was found in:

- Kaji et al, Bull. Chem. Soc Jpn, 49, pp3181-3184 (1976)
- Rich et al, Journal of Org. Chem., 45, pp 2288-2290 (1980)
- Craig et al, US patent 6242494.
- Matsuda et al, Bull. Chem. Soc. Jpn. 655 (2) pp 360-365 (1992)
- Peet et al, J. Med. Chemistry, 33(1) pp 394-407 (1990) and
- Ojima et al, Tetrahedron Letters, 33 (39) pp5537-5700 (1992).

Kaji discloses 3-amino-2-hydroxy carboxylic acid derivatives; Rich discloses 3-amino-2-hydroxy-5-methylhexanoic acid. Similarly, Craig discloses 3-amino-2-hydroxy-5-ethylthio pentanoic acid and Matsuda discloses a series of 3-amino -2- hydroxy carboxylic acids. Likewise, Peet discloses some inhibitors of porcine pancreatic and its

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synthesis. As part of the said synthetic route, Peet discloses as an intermediate, methyl 3-amino-2-hydroxy butanoate. Furthermore Ojima discloses a series of 3-amino-2-hydroxy carboxylates salts and its use as peptide-based inhibitors of various enzymes.

None of these cited references however teach or suggest hydroxy alkyl amino carboxylic acid derivatives embraced by the definition described in the instant claims.

### **CONCLUSION**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

All post-Allowance Correspondence concerning this Application must be mailed to:

**BOX ISSUE FEE  
COMMISSIONER FOR PATENTS  
WASHINGTON, DC 20231**

Or you can fax them to the Office of Patent Publications at 703-308-5083, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

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For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027.

Héctor M. Reyes, PhD JD

Ms. Cecilia Tsang

AU 1625  
April 13, 2005

Supervisor Patent Examiner



CEILA CHANG  
PRIMARY EXAMINER, Acting SPE  
GROUP 1200